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Del Mar Reynolds Medical Ltd.
Special 510(k) Submission
Sentinel
510(k) Summary

JAN 25 2007

(1) Submitter Information

Name: DelMar Reynolds Medical Ltd.

Address:

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John Tate Court
Hertford, Herts SG137NW
ENGLAND

Telephone Number: 44-1992-507700

Contact Person:
Dr. George Myers (Official Correspondent)
Medsys Inc.
377 Route 17 S
Hasbrouck Heights, NJ 07604
Telephone 201-727-1703
Fax 201-727-1708

Date Prepared: July 27, 2006

(2) Name of Device

Trade Name: Sentinel
Common Name: Central Data Base for Cardiology Devices
Classification name: Computers and Software, Medical

(3) Equivalent legally-marketed devices.

1. DelMar Reynolds CardioNavigator Plus, K051960

(4) Description

Sentinel, a software product, is a computer program intended to organize and manage the databases for compatible Reynolds Monitoring products and also to act as a "control panel" for these products. The software

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that formerly was used with these devices has been transferred to sections of Sentinel. The program itself can be applied with all products.

The individual products are all data-gathering devices used to collect cardiology patient data (ECG or blood pressure). These devices were previously sold with dedicated software programs that allow the devices to be set-up or configured both to program the devices, and to receive downloaded data from the devices and produce reports. In general, the dedicated programs also have a database uniquely for data from that device. As noted before, these dedicated data bases are replaced by the Sentinel database.

Sentinel maintains a common cardiology database for the data collected by the compatible devices, and also permits the user to operate the various devices in a manner identical to the way they were operated as individual products. As a common data base, Sentinel stores data collected from each patient in the section of the database dedicated to that patient. When used as a method for operating the device, the user selects the icon associated with the device. The user then sees the opening screen for the operation of that device, and all succeeding screens, as they were seen when the device was used with its dedicated program.

Sentinel has no capacity for analyzing electrocardiograms. When Sentinel is used with the Pathfinder Holter Analysis program, the Pathfinder program is loaded into the same computer, and Pathfinder can be called by Sentinel, but there are no other control links

Sentinel can be used on a personal computer (PC) that meets specifications established by Del Mar Reynolds Medical. Sentinel will work with products already owned by the user, or with new products (included in the list of compatible products) that the user may purchase later.

Sentinel will work on a single computer, but it has been re-configured to be also used in a network

(5) Intended Use

Sentinel, a software product, is a computer program intended to organize and manage the databases for compatible Del Mar Reynolds Medical Monitoring products and also to act as a "control panel" for these products. It is indicated when a user wishes to consolidate the databases of his Del Mar Reynolds Medical products.

(6) Performance Data

(a) Non-clinical tests

Sentinel has been extensively validated by itself and in conjunction with the associated Del Mar Reynolds Medical devices.

(b) Clinical tests

Clinical tests are not necessary, since Sentinel uses the same technology as the predicate device.

(c) Conclusions

Sentinel is equivalent in safety and efficacy to the legally-marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Medsys, Inc.
c/o Dr. George Myers
Official Correspondent
377 Route 17 S
Hasbrouck Heights, NJ 07604

Re: K062397
Trade Name: Sentinel
Regulation Number: 21 CFR 870.2920
Regulation Name: Telephone electrocardiograph transmitter and receiver
Regulatory Class: Class II (two)
Product Code: DXH
Dated: January 5, 2007
Received: January 8, 2007

Dear Mr. Myers:

This letter corrects our substantially equivalent letter of January 25, 2006.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In

addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-4001. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

B Zuckerman for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Indications for Use

510(k) Number (if known): K062397

Device Name: Sentinel

Indications for Use:

Sentinel, a software product, is a computer program intended to organize and manage the databases for compatible Del Mar Reynolds Medical Monitoring products and also to act as a "control panel" for these products. It is indicated when a user wishes to consolidate the databases of his Del Mar Reynolds Medical products.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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